Reference number
2288-A

SPECIALTY GUIDELINE MANAGEMENT

DACOGEN (decitabine)
decitabine (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Myelodysplastic syndromes (MDS): Dacogen (decitabine) is indicated for treatment of adult patients with myelodysplastic syndromes (MDS) including previously treated and untreated, *de novo* and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

B. Compendial Uses
1. Acute myeloid leukemia (AML)
2. Accelerated phase or blast phase myelofibrosis
3. Lower risk myelodysplastic syndromes (MDS) associated with thrombocytopenia, neutropenia, symptomatic anemia, or increased marrow blasts
4. Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
5. Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) Overlap Neoplasms

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Myelodysplastic syndromes (MDS)
Authorization of 12 months may be granted for the treatment of MDS.

B. Acute myeloid leukemia (AML)
Authorization of 12 months may be granted for the treatment of AML.

C. Accelerated phase or blast phase myelofibrosis
Authorization of 12 months may be granted for the treatment of accelerated phase or blast phase myelofibrosis.

D. Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Authorization of 12 months may be granted for the treatment of BPDCN when used in combination with venetoclax in either of the following settings:
1. For the treatment of relapsed or refractory disease.
2. For the treatment of systemic disease with palliative intent.

E. Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) overlap neoplasms

Authorization of 12 months may be granted for the treatment of MDS/MPN overlap neoplasms (i.e. chronic myelomonocytic leukemia (CMML), BCR-ABL negative atypical chronic myeloid leukemia (aCML), unclassifiable MDS/MPN, or MDS/MPN with ring sideroblasts and thrombocytosis).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Dacogen [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; June 2020.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed January 4, 2021.